REMARKS

I. Status of the Claims

Claims 1-17 are pending in this application. Claims 1-4, 7-9, 11, 16 and 17 were rejected and claims 5, 6, 10, and 12-15 were objected to in the Office Action dated February 25, 2004. Claim 1 has been amended to respond to rejections for use of the terms "GPS" and "GPM." Support for this amendment can be found on page 4 of the specification, especially at lines 8-9. Further, Applicants have amended claims 3-17 to remove multiple dependencies. Applicants respectfully request consideration and examination of this application and the timely allowance of the pending claims in view of the arguments below.

II. Suggestion of Compliance with 37 C.F.R. 1.77(b) and Objection to the Disclosure for Lack of Separate Description of Drawings

The Examiner has suggested that Applicants adhere to the guidelines outlining the preferred layout for the specification. (2/25/04 Office Action at 2.) The instant application is based on German Application No. 19943491.3, originally structured for filing in the German patent office. Because the application was not originally structured to accommodate these preferred headings, their inclusion could create inaccurate subdivisions within the instant specification. Applicants note the suggested specification layout, although preferred by the Office, is not required. Therefore, to avoid possible

error and confusion, Applicants demur from adding section headings not present in the original German application and respectfully request the withdrawal of this objection.

The Office has also objected to the disclosure because there is "no separate description of the figures in the specification." (2/25/04 Office Action at 3.) Applicants note that the drawings are described at pages 13-14.

III. Objection to the Drawings

The Office has objected the drawings submitted with the application because they are in German. (2/25/04 Office Action at 3.) Applicants have submitted translated copies of the drawings. Accordingly, Applicants respectfully request withdrawal of this objection.

IV. Rejection of Claim 1 under 35 U.S.C. § 112, ¶ 2

Claim 1 was rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite. (2/25/04 Office Action at 3.) Particularly, the Office states that Applicants' use of the terms "GPS" and "GPM" render the claims indefinite because "it is unclear what is meant by these terms." Although Applicants believe that the meaning of these terms is clear in light of the specification, e.g. page 4, lines 8-9, Applicants have amended Claim 1 to identify the compounds 6-O-α-D-glucopyranosyl-D-sorbitol and 1-O-α-D-glucopyranosyl-D-mannitol. Accordingly, Applicants respectfully request withdrawal of this rejection.

V. Rejection of Claims 1-4, 7-9, 11, 16 and 17 under 35 U.S.C.§ 103(a)

Claims 1-4, 7-9, 11, 16 and 17 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over "Lindley (US 4,572,936)". (2/25/04 Office Action at 4.) Applicants traverse this rejection. Applicants note that there appears to be an inadvertent error in that Lindley as cited on the PTO-892 is US 4,572,916.

Applicants submit that the Office's §103(a) rejection of claims 1-4, 7-9, 11, 16 and 17 does not meet the basic criteria of a *prima facie* case of obviousness. In order for the Office to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *See* M.P.E.P. § 2143. Further, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In the present case, the Office has not pointed to a basis in the cited reference that would have led one of ordinary skill in the art to Applicants' invention. For the reasons set forth below, Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness.

Claim 1 recites "[a] method of producing a compressed product" and requires as a method step the dry grinding of isomaltulose, isomalt, or a mixture containing 1,6-GPS and 1,1-GPM. Claim 1 then further requires a method step of obtaining or separating a

ground fraction of isomaltulose, isomalt, or a mixture containing 1,6-GPS and 1,1-GPM "with a maximum particle diameter of 100 μm." Claims 3 and 4 further limit the maximum particle size used in the method of claim 1. Lindley et al. do not teach that the isomaltulose used should be ground dry. In addition, and as acknowledged by the Examiner, Lindley et al. do not teach that the isomaltulose used in the method of Lindley et al. should have a maximum diameter of 100 μm, as recited in independent claim 1. (2/25/04 Office Action at 4.) The Examiner contends, however, that "[c]hange in the particle size of the intermediate product is not alone seen to constitute unobviousness, particularly when the final product is compressed into a larger sized product." (2/25/04 Office Action at 4.)

However, besides failing to teach the recited method steps of dry grinding and then of separating or obtaining particles from the ground fraction with a maximum diameter of 100 μm, Lindley et al. do not provide any suggestion or guidance such that the ordinary artisan would conclude that a maximum particle size of 100 μm was critical to the use of isomaltulose in tablet formation. Lindley et al. do not teach that the isomaltuose should be ground for use in tablet production. Lindley et al. do not teach a maximum diameter of the isomaltulose particles that can be used in the method. Neither do Lindley et al. suggest that the diameter of the isomaltulose particle used is important. To the contrary, Lindley et al. appear to consider the characteristics of the isomaltulose used in the method to be of little importance. For example, Lindley et al. teach at column 4, lines 24-40, that the isomaltulose is in crystallized form and need not be pure. At column 2, lines 20-25, Lindley et al. explicitly state that an object of their

invention is to provide a direct compression vehicle which does not require special preparation or treatment before mixing with an active ingredient and subsequent tabletting. Because Lindley et al. do not in any way suggest that the isomaltulose particle diameter is important, the ordinary artisan would not be motivated from the teachings of Lindley et al. to dry grind the isomaltulose and then obtain or separate a ground fraction of isomaltulose with a maximum particle diameter of 100 μm for use in a method of producing a compressed product containing isomaltulose. Instead, it is only in view of the guidance provided in the instant disclosure that the ordinary artisan would be motivated to include these additional steps.

The Office cites Lindley et al. for its teaching that "[a]fter thorough mixing, the mixture was passed through a size 16 mesh sieve (1000 microns) and dried at 95° C. to give a tablet base composition." (2/25/04 Office Action at 4, quoting Lindley et al. at col. 5, lines 55-58.) The Office states that the claims appear to differ from the reference in the suggestion of a smaller particle size ground intermediate composition. (2/25/04 Office Action at 4.) Lindley et al. at col. 5, lines 55-58, however, describes particle size fractionation of an *agglomerate*. This is different from the dry ground fraction of the isomaltulose, the isomalt, or the mixture containing 1,6-GPS and 1,1-GPM with a maximum particle diameter of 100 μm that is obtained or separated in step b) of claim 1. Instead, in the instant invention size separation of the agglomerate is a second, different, optional step. (See page 7, lines 15-21; Claim 13.) This second optional step is not limited to a maximum particle diameter of 100 μm. (*Id.*) Size fractionation of the agglomerate disclosed in Lindley et al. is therefore different from, and does not teach or

suggest, the separating or obtaining the dry ground fraction of the isomaltulose, the isomalt, or the mixture containing 1,6-GPS and 1,1-GPM with a maximum particle diameter of 100 μm in step b) of claim 1.

Besides failing to identify the importance of the isomaltulose particle diameter, Lindley et al. also provide a working example in which the particle diameter used is outside the particle diameter required in Applicants' method. Example 1 of Lindley et al. teaches the utilization of a pasty mixture of isomaltulose and gum arabic solution that is pressed through a 16 mesh sieve (1000 μm) and dried at 95°C to give a tablet base composition. (Col. 5, l. 51 - col. 6, l. 9.) The ground fraction of this composition to be compressed in Lindley et al. must contain particles the diameter of which is larger than the 100 μm maximum recited in the instant claims. Given a working example that uses isomaltulose particles larger than the 100 μm maximum recited in the instant claims, the ordinary artisan would not be motivated from the teachings of Lindley et al. to obtain or separate particles with a maximum diameter of 100 μm, as required by the instant claims.

The Examiner notes that Applicants indicate that the particle size is important to the present invention, but the Examiner asserts that the criticality of the particle size is not shown in the specification. (2/25/04 Office Action at 5.) Applicants point out that the steps of dry grinding and then obtaining or separating particles from the ground fraction of a particular size are claimed limitations. Each of these limitations in the independent claim must be taught or suggested by the prior art to render the claim unpatentable. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) and M.P.E.P. § 2143.03.

In addition, Applicants direct the Examiner's attention to page 3 of the specification which states in its description of the invention that the adjustment of the primary particle size distribution according to the present invention is extremely important. In their discussion of Figure 3 on page 14 of the specification, Applicants further emphasize the importance of using particles with a diameter of less than 100 μm.

Lindley et al. fail to either teach or suggest that the ordinary artisan should include as method steps dry grinding the isomaltulose and then obtaining or separating a specific subset of particles which have a maximum diameter of 100 μm, as recited in independent claim 1. Because Applicants' method utilizes only this specific subset of isomaltulose particles which is neither taught nor suggested by Lindley et al, the products recited in claims 16 and 17 necessarily differ from the products produced by Lindley et al. For example, the instant specification discloses that by limiting the diameter of the particles used, the tablets obtained by the disclosed method have the unexpected property of a smooth, rather than rough, surface and that this is an advantageous property of the tablets produced according to the instant method relative to the tablets produced by the methods of the prior art. *See* Figure 3, "sensory properties" and the specification at page 2. In addition, the specification on page 2 describes other unexpected properties of tablets produced by a method that limits the particle size used to a maximum diameter of 100 μm, including improved tablet hardness, improved fracture behavior, and a reduced pressing force requirement for their production. In contrast, Lindley et al. do not describe these qualities as properties of their claimed tablets, and instead teach that tablets made by the method of Lindley et

al. did not perform well when tablet hardness was evaluated. (Col. 8, ll. 22-63.) These unexpected beneficial properties of Applicants' tablets compared to the tablets produced by the method of Lindley et al., particularly the increased tablet hardness, establish that the products produced by the two methods are not the same.

The teachings of Lindley et al. fail to teach or suggest claimed steps of Applicants' method. In addition, the products produced by Applicants' method have properties that unexpectedly differ from the products produced by Lindley et al. Therefore, the instant claims are novel and unobvious in view of the teachings of Lindley et al. Accordingly, Applicants respectfully request withdrawal of this rejection.

VI. Objection to Claims 5, 6, 10, and 12-15 as Dependent Upon Rejected Base Claim

The Examiner has objected to Claims 5, 6, 10, and 12-15 as being dependent upon a rejected base claim. (2/25/04 Office Action at 5.) Applicants have traversed the rejection of the base claim, and believe that the base claim is now allowable. Applicants therefore respectfully request withdrawal of the objection.

VII. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: June 23, 2004

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Attachments: Replacement Drawings (Figures 1-3; 3 pages)